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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/405,499 | 09/23/1999 | MICHAEL S. O'REILLY | 05213-0640 | 9544 |

23594 7590 05/29/2003

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EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 05/29/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|-----------------|
| Office Action Summary | Application N . | Applicant(s) |
| | 09/405,499 | O'REILLY ET AL. |
| | Examiner | Art Unit |
| | Sheela J Huff | 1642 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 31 March 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 52-55,57-66 and 68-73 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 52-55,57-66 and 68-73 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s). _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

The previous office action has been vacated in view of the amendment filed 3/31/03. This amendment did not reach the Examiner before 4/9/03 (the mail date of the final action). In view of the above, the finality of the previous action is removed and the amendment filed 3/31/03 has been fully considered.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/19/03 has been entered.

Claims 52-55, 57-66 and 68-73 are pending.

The new matter rejection under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's amendment.

The art rejection is withdrawn in view of applicant's amendment.

Response to Arguments

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

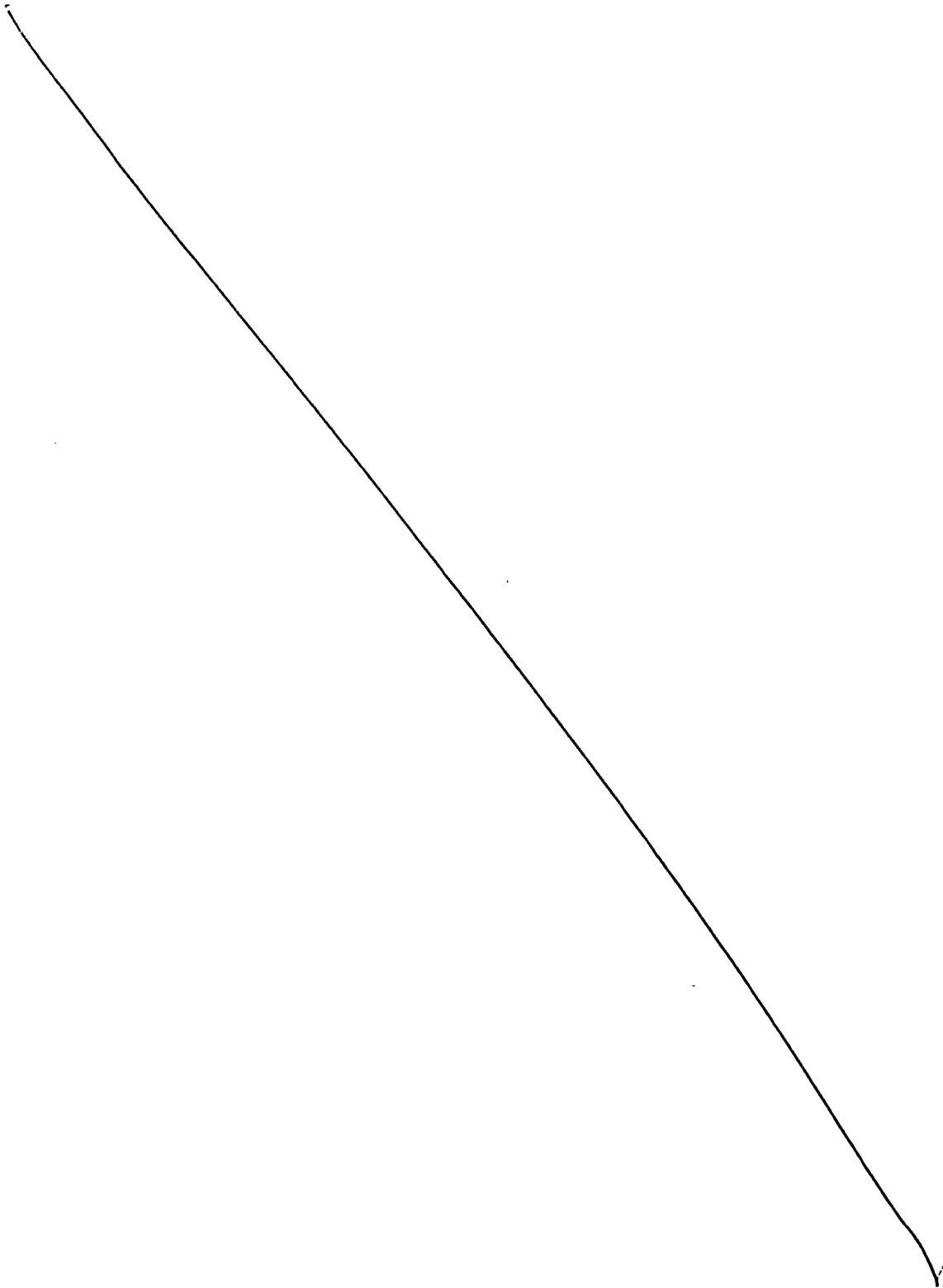
Claims 52-55, 57-66 and 68-73 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 17-23 of U.S. Patent No. 5854205. The reasons for this rejection are of record in paper no. 5, mailed 12/19/00.

Applicant indicates that terminal disclaimers will be filed.

Claims 52-55, 57-66 and 68-73 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of US. Patent No. 6346510. The reasons for this rejection are of record in paper no. 5, mailed 12/19/00.

Applicant indicates that terminal disclaimers will be filed.

Claim Rejections - 35 USC § 112



Claims 52-55, 57-66 and 68-73 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for endostatin (as defined by its molecular weight, N-terminal sequence and ability to inhibit endothelial cell proliferation in vitro), does not reasonably provide enablement for a protein comprising or consisting of any fragment of NC1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The reasons for this rejection are of record in paper no. 9, mailed 7/19/01.

Applicant argues that the term "NC1" is well defined in the specification, particularly at page 37, lines 3-15. This section defines "NC1" in terms of collagen XVIII only.

Applicant argues that the common structural element is that all fragments have a C-terminal non-collagenous region. Applicant further argues that endostatin is defined on pages 11-15 and that collagen may be isolated from other collages and from other proteins (page 53). On page 14, endostatin is defined in terms of its N-terminal sequence and as discussed in the previous actions the sequence in the 18 collagens is different.

Applicant argues that the common functional feature is that each fragment possess antiangiogenic activity. Due the number of collagens and in view of the lack of common structural features between the collagens, one skilled in the art would need to test each and every one. This is undue experimentation.

Claims 52-55, 57-66 and 68-73 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The reasons for this rejection are of record in paper no. 9, mailed 7/19/01.

Applicant argues that the specification teaches how to isolate and test fragments and has given specific examples in the form of SEQ ID no. 1 and 2. Seq ID No. 1 and 2 are from collagen XVIII and there is no common structural feature that correlates to function or to applicant having possession of the genus now claimed.

Applicant argues that the lack of homology between the collagen molecules support their inventions' novelty and patentability. While applicant's invention is novel and unobvious, the remaining requirements under 35 U.S.C. 112, first paragraph, have not been fully met.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 703-305-7866. The examiner can normally be reached on T,Th 6am-12pm and alternate Mondays 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone

numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Sheela J. Huff
Primary Examiner
Art Unit 1642

sjh
May 27, 2003